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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jill Lynn Woodburn
Roche Diagnostics Corporation
9115 Hague Road Building D
PO Box 50457
Indianapolis, IN 46250-0457

EXAMINER

QUAN, ELIZABETH S

ART UNIT

PAPER NUMBER

1743

6

DATE MAILED: 04/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,793

Applicant(s)

ZIMMER, VOLKER

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-5,7 and 9-16 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second notch must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because the first sentence is a run-on. Furthermore, it is not necessary to include "samples" in the second line of the abstract. Correction is required. See MPEP § 608.01(b).

4. The specification is not arranged in the specific categories listed below, such as BACKGROUND OF THE INVENTION, BRIEF SUMMARY OF THE INVENTION, BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S), and DETAILED DESCRIPTION OF THE INVENTION.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

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As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. The disclosure is objected to because of the following informalities: On page 1 in the second line of the first paragraph "samples" could be omitted. On page 1 in the third line of the third paragraph "elongate" could be replaced by "elongated." On page 3 in the sixth line of the of first paragraph "lccomplished" should be replaced by "accomplished." The sentence is also long and difficult to comprehend. On page 3 in the tenth line of the second paragraph " , cut" could be omitted. On page 4 in line 13 of the second paragraph "edge" should be replaced by "edges." The paragraph also consists of a single confusing sentence. On page 4 in line 3 of the

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third paragraph "realised" could be replaced by "realized." On page 5 in the last sentence of the second paragraph "...and the surface on hydrophobic i.e. water repellent surfaces" is not clear. On page 6 in lines 1-4 of the first paragraph the following sentence does not make sense... "If the value of the surface tension of the observed surface is much below this value (72 mN/m) i.e. more than 20 mN/m..." Is the optimum range 20 mN/m - 72 mN/m? On page 9 in line 9 of the first paragraph "...oxidized to form the oxidized form" is redundant. On page 9 in line 5 of the second paragraph "firstly" could be omitted. On page 11 in the lines 1-6 of the second paragraph the sentence is confusing... Is a homogeneous sample distribution over the detection element directly resultant of sample liquid contacting the whole area of the detection element? On page 12 in the first line of the second paragraph "detail" should probably be "detailed."

Appropriate correction is required.

Claim Objections

6. Claims 2 and 3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. While the dependent claims 2 and 3 recite limitations for more than one notch, only a single notch was recited in parent claim 9.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Both the specification and drawings do not disclose nor show more than one notch. It is not clear whether the second notch is the vent hole or another sample application opening to conduct a second and separation sample liquid analysis.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-5, 7, and 9-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 9 and 16 recite the limitation "one of the surfaces" in the fifth and fourth lines of the claims, respectively. There is insufficient antecedent basis for this limitation in the claim. Surfaces have not been recited as an element in the claim.

12. Claim 3 recites the limitation "notches" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Parent claim 9 recites a single notch.

13. Regarding claim 4, the phrase "capable" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

14. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural

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cooperative relationships are: sample application opening, surfaces forming the channel, and the notch. It is unclear what surface is referred to in "the surface opposed to the notch is exposed." It is also unclear how one side of the edge of the sample application opening is at least partially discontinuous.

15. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: sample application opening, surfaces forming the channel, and the notch. It is unclear what surface is referred to in "the surface opposed to the notch is exposed." It is also unclear how one side of the edge of the sample application opening is at least partially discontinuous. Additionally, it is not clear how the sample application opening is broken by the notch.

16. Claims 2-5 and 7 are rejected based on their dependency on rejected parent claims.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 4, 5, 9-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,952,373 to Sugarman et al.

Referring to claims 4, 5, 9-14, and 16, Sugarman et al. disclose a liquid diagnostic device with the leading edge (11) of the liquid shield (10) projecting upward from a

substantially flat upper surface (21) of the cartridge (20) (see FIGS. 1-5; COL. 3, lines 15-18). A portion (14) of the shield (10) is attached at an edge of the liquid receiving well (22) (see FIGS. 1-5; COL. 4, lines 23-25). While the shield (10) is primarily for confining sample liquid in the receiving well (22), the shield (10) may fulfill the auxiliary function of blocking light from reaching the surface (31) of the monitor and/or the gap (32) between the cartridge surface (21) and monitor surface (31) (see COL. 3, lines 40-45; COL. 4, lines 50-60). When one or two drops of blood is applied to the well (22) in the cartridge (20), the liquid automatically flows into a chamber containing reagent and continues traveling through a capillary path until the blood coagulates (see FIGS. 1-5; COL. 2, lines 61-67). Therefore, Sugarman et al. include all the limitations in claims ~~1-16~~ 4, 5, 9-14 and 16.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al.

Referring to claims 2 and 3, Sugarman et al. do not disclose a plurality of notches. Applying the decision made by the Federal Circuit in *Gardner v. TEC Systems, Inc.*, the number of notches would not affect the performance of the claimed device respective to the prior art device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the number of notches as necessary to perform the desired amount of assays. Therefore, the claimed device is not patentably distinct from prior art device based on the number of notches.

22. Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,952,373 to Sugarman et al. as applied to claims 12 and 14 above, and further in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claims 7 and 15, Sugarman et al. do not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-

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19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the device of Sugarman et al. to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art includes one or more limitations recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

Elizabeth Quan
Examiner
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March 21, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700